

DRAFT - April 12, 1989

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DRAFT STATEMENT CONCERNING INGREDIENTS  
FOR USE BEFORE A CONGRESSIONAL COMMITTEE

I am appearing today on behalf of the six major American cigarette manufacturers to discuss the use of ingredients that are added to tobacco in the manufacture of cigarettes. I will briefly explain the tobacco industry's record of cooperation with the federal government concerning ingredients, and will then describe the ways in which ingredients are used and the information available concerning the safety of ingredients.

Background

In recent years, the major American cigarette manufacturers have regularly cooperated with the Federal Government concerning ingredients. For example, in 1982, representatives of the Office on Smoking and Health of the Department of Health and Human Services ("HHS") reviewed a list of the most commonly used ingredients that was voluntarily provided by the cigarette manufacturers under an agreement with Dr. Edward N. Brandt, Jr., then Assistant Secretary for Health at HHS. The manufacturers informed HHS at the time that they were prepared to work with HHS as it

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reviewed the list, but HHS did not communicate with the industry regarding any review undertaken by the Agency.

In 1984, the Comprehensive Smoking Education Act was passed. The Act mandated the periodic submission to HHS of lists of ingredients, and the cigarette manufacturers have complied fully with the requirements of the Act. In April 1986 the manufacturers submitted a comprehensive ingredient list to HHS pursuant to the Act, and since that time they have submitted an updated list each December. In submitting each of these lists, the manufacturers informed HHS that industry representatives were available to consult with HHS about the ingredients on the list, and to participate in the review of ingredients by HHS.

Despite the industry's willingness to participate, HHS never invited the industry to assist in a review of ingredients. Rather, HHS prepared its report without the assistance of the industry scientists who are most knowledgeable about the use of ingredients. This failure resulted in a report that, we respectfully submit, is inaccurate.

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### Use of Ingredients

Non-tobacco ingredients have been employed in cigarettes for many decades. Flavoring ingredients have been used in tobacco for as long as people have smoked. When Europeans first learned about smoking tobacco from the Indians, the tobacco they smoked was flavored with citrus peels and other natural spices and herbs. In the United States, the use of flavorings has been a common practice since colonial times. Manufactured cigarettes, which were first introduced in the United States in the early 1900's, have always been blended and flavored with non-tobacco ingredients.

The use of non-tobacco ingredients in cigarettes is well-known to persons familiar with the tobacco industry and has been the subject of reports in the popular press and discussion in the Reports of the Surgeon General of the United States. However, the specific ingredients in particular cigarette products are closely-guarded trade secrets. It is those ingredients, together with the particular tobacco blend, that give each brand and style of cigarette its distinctive taste and aroma. The Comprehensive Smoking Education Act of 1984 recognizes that cigarette ingredient information is an important trade secret, and HHS regulations prohibit the disclosure to the public of cigarette ingredient data.

Ingredients are used for a number of purposes in the manufacture of cigarettes. Ingredients are added to cigarettes to enhance smoking enjoyment and pleasure. Without

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ingredients, smokers would not have the current choice of a wide range of flavors and "tar" and nicotine levels.

Ingredients are also necessary to assure the uniformity and high quality of cigarette products.

There are three principal types of non-tobacco ingredients employed in cigarettes. Casings and humectants are added to replace sugars lost during curing of tobacco, to retain moisture, to add flavor, to aid in processing, and to make the smoke smoother and milder. Sugars contribute acidic components that reduce the pH of smoke and make cigarette smoke milder. Humectants improve the burning qualities of cigarettes. Without humectants, cigarettes would burn much more rapidly and at higher temperatures, thereby decreasing smoking pleasure. Casings and humectants are typically used in quantities from 3 - 10% by weight of the blend. All of the casings and humectants used by American cigarette manufacturers are foods, food products, or ingredients approved for food use by the United States Food and Drug Administration (FDA).

Top dressing flavorings are added to fortify natural tobacco flavors lost during curing and processing and to impart specific, distinctive flavor notes in particular products, such as menthol. The cigarettes manufactured earlier in this century contained top dressings composed primarily of foods and natural herbs and spices or the essential oils derived therefrom. Today, cigarettes, like

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foods, also contain a variety of artificial flavors. Top dressing flavorings are generally used at extremely low, parts per million ("ppm"), levels. The extremely small quantity represented by 1 ppm can be illustrated by the fact that it equates to one second in eleven days.

Processing aids are used to adjust products to meet consumer demands. The use of processing aids enables manufacturers to produce products which are relatively uniform in "tar" and nicotine content, and to achieve lower levels of "tar" and nicotine than would be possible without those aids. Most processing aids are recovered during manufacturing. However, residual amounts, generally in the ppm range, may remain in the tobacco after processing.

The average "tar" and nicotine content of cigarettes sold today is substantially (up to 300%) below that of cigarettes sold in the 1950s. Processing aids enabled the industry to control "tar" and nicotine content, and the use of flavoring ingredients enabled manufacturers to offer "low-tar" cigarettes with enhanced flavor and aroma. This was confirmed in the 1981 Report of the Surgeon General, p. 99 ("The development of lower 'tar' and nicotine cigarettes has tended to yield products that lacked the taste components to which the smoker became accustomed. In order to keep such products acceptable to the consumer, the manufacturers reconstitute aroma or flavor.") and the 1984 Report of the Surgeon General, p. 352 ("When initially introduced, lower yield cigarettes

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lacked palatability and acceptability. Advertisements for the current low tar and nicotine cigarettes emphasize their flavor, presumably achieved by the use of additives in the processing of tobacco.").

The lists of ingredients that have been submitted by the industry to HHS contain many compounds, but about 20 of the ingredients comprise approximately 99% of the total amount, by weight, of ingredients used by the industry. Most other ingredients are used in much smaller amounts, in many cases only as components of flavor formulations. There may be a large number of ingredients in a particular flavor formulation, but typical industry-wide usage of most of the ingredients found in these flavors is under 10 pounds per year. This is in contrast with the over 900 million pounds of tobacco employed in cigarettes sold in the United States each year. Particular flavoring ingredients are added or eliminated from time to time as new products are introduced or existing products are reformulated in response to changing consumer preferences.

In addition, while a large number of ingredients are used, it is important to note that ingredients do not comprise a significant portion of the final cigarette. For example, processing aids, which typically are used in large amounts, are greatly reduced during the manufacturing process. Such processing aids remain in the final cigarette in minute quantities, if at all.

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Similarly, as noted above, a large number of the ingredients are used as flavors, but these substances typically appear in the final cigarette in minuscule amounts. Flavor ingredients will normally constitute less than one-tenth of one percent by weight of the final product, and all ingredients, including casing materials, humectants, and the few major flavors, will typically comprise no more than 5% by weight of the cigarette.

#### Health Effects of Ingredients

The key question of interest to this Committee is, of course, the health effects of the ingredients being used. Contrary to the HHS report, it is our view that these ingredients as used in cigarettes are not harmful. HHS appears simply to have failed to consider the evidence that supports this view.

Virtually all of the ingredients used by American cigarette manufacturers are foods, normal components of foods, ingredients approved for addition to foods by FDA and/or expert bodies as Generally Recognized as Safe (GRAS) for human consumption, and/or normal constituents of tobacco leaf or smoke. The few ingredients that do not fall within one or more of these categories have been carefully evaluated by scientists employed by the tobacco industry and determined not to present any measurable risk under the conditions of use in cigarettes.

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It is well accepted by the scientific community that toxicity is a function of dose and that many compounds are toxic at very high dose levels but not at the lower levels to which humans are ordinarily exposed. This is true of naturally occurring and added substances in food and equally true of the ingredients employed in cigarettes.

The non-tobacco ingredients added to cigarettes which are foods, food components or GRAS ingredients have been shown to be safe for consumption as part of the human diet. The level of exposure to these ingredients in cigarettes is very low in comparison to exposure from food. In general, the transfer rate of non-tobacco ingredients into mainstream smoke is only 10-15%, and approximately one-half of that amount is expelled immediately through exhalation. Given the food use of most non-tobacco ingredients employed in cigarettes, the low levels of ingredients used in cigarettes and the much lower rate of retention by smokers, it is our view that smokers are not exposed to any measurable health risk from non-tobacco ingredients in cigarettes.

The available evidence suggests that non-tobacco ingredients tend to decrease the biological activity of cigarette smoke condensate. Moreover, as noted, use of non-tobacco ingredients has enabled manufacturers to produce low "tar" cigarettes that are still palatable to consumers.

Flavors that are normal constituents of tobacco smoke or leaf are added in amounts far below their

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naturally-occurring level, and there is no evidence that they are harmful.

None of the ingredients used by the companies for which I am appearing has been determined to be a carcinogen. This does not mean that questions have not been raised from time to time with respect to specific ingredients. Every scientist knows that from time to time questions will be raised about the safety of particular substances. Where such questions have been raised, they have been answered with a determination that the substance is not carcinogenic.

In addition, I do not believe that any of the ingredients are mutagenic or teratogenic. A few of them may have tested positive in mutagenicity screening tests. Where this is the case, more extensive research has generally shown that the compound is not mutagenic. None of the compounds is recognized as a known teratogen.

Most of the ingredients are used in a wide variety of consumer products. As noted, most of them have been reviewed by FDA, and are specifically approved for use in foods. Many are also approved by quasi-regulatory bodies, such as trade groups and scientific organizations, which are recognized by the Food and Drug Administration for their expertise concerning ingredients. Many of the ingredients are used in other consumer products.

In addition, many of the ingredients are approved for use in tobacco products by regulatory authorities in other

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countries. For example, the Independent Scientific Committee on Smoking and Health in Great Britain publishes a list, commonly referred to as the Hunter-Froggatt List, of ingredients that are approved for use in cigarettes. Germany also approves cigarette ingredients.

Internal Review of Ingredients  
by Tobacco Manufacturers

I also would like to describe briefly the steps that the tobacco industry has taken to insure that only proper ingredients are used. Ingredients have been of interest to regulatory authorities since the early 1980's, but they have been of interest to cigarette manufacturers far longer. Each company has had its own review mechanism for ingredients, and each has carefully selected the ingredients it uses. These decisions are made by each company individually, of course, since the identity of ingredients is an important trade secret.

The companies have carefully reviewed each ingredient and concluded that none of them raises health concerns. This conclusion is based upon the available scientific evidence for specific ingredients, including information from the public literature and information developed by the companies. The companies have considerable scientific resources, and have utilized those resources where necessary.

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One beneficial feature of this review has been a reduction in the number of ingredients in use. Nearly all formulation changes resulted from the discovery that the same flavor effect could be obtained by using fewer ingredients. The companies have worked to ensure that only those ingredients that are necessary to produce the desired flavors are being used.

I would be happy to answer your questions about ingredients, as would the gentlemen with me who are industry scientists.

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